Human Subjects Testing

- **Physical and privacy protection of human subjects is of utmost importance**
  - **Human subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information**
  - **Research means systematic investigation (including research, development, testing and evaluation) designed to develop generalizable knowledge**
- **Institutions must provide an "Assurance of Compliance" with federal policies to the federal sponsor. The required features of an assurance are:**
  - **A statement of principles governing the institution's responsibilities**
  - **Designating and providing for Institutional Review Board (IRB)**
  - **List of IRB members and their biographical information**
  - **Written procedures describing the review processes**
  - **Written procedures for reporting problems or suspensions**
- **An institution must submit a "Certificate" to the sponsor prior to the initiation of research**
  - **The certificate must state that the protocol has been reviewed and approved by the IRB provided for in their assurance**
  - **Multi-year research requires submission of a Certificate at least annually, or more frequently if deemed necessary by the IRB**
- **A DARPA instruction is in development to implement the higher-level guidance for the protection of human subjects**

Human Subjects Testing

- References (available on the internet)
  - DoD Directive 3216.2, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” March 25, 2002
  - DoD 3210.6-R, “DoD Grant and Agreement Regulations,” April 13, 1998
  - Title 32, Code of Federal Regulations, Part 219, “Protection of Human Subjects,” current edition
  - Section 980 of Title 10, United States Code
  - Title 45, Code of Federal Regulations, Part 46, “Protection of Human Subjects”, current edition
  - DoD Directive 6200.2, “Use of Investigational New Drugs for Force Health Protection,” August 1, 2000
  - DoD Directive 6000.8, “Funding and Administration of Clinical Investigation Programs,” November 3, 1999